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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  004974.01083			
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		Application Number  10/528,460	Filed  December 19, 2005		
		First Named Inventor  Golz			
		Art Unit  1657	Examiner  Bin Shen		
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%; border: none;"><tr><td style="width: 50%; vertical-align: top; padding: 5px;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input checked="" type="checkbox"/> attorney or agent of record.      42,653 Registration number _____</p><p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p></td><td style="width: 50%; vertical-align: top; padding: 5px; border-top: 1px solid black;"><p style="text-align: right;">/Lisa M. Hemmendinger/</p><hr/><p style="text-align: center;">Signature</p><p style="text-align: center;">Lisa M. Hemmendinger</p><hr/><p style="text-align: center;">Typed or printed name</p><p style="text-align: center;">202-824-3000</p><hr/><p style="text-align: center;">Telephone number</p><p style="text-align: center;">July 3, 2007</p><hr/><p style="text-align: center;">Date</p></td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record.      42,653 Registration number _____</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>	<p style="text-align: right;">/Lisa M. Hemmendinger/</p> <hr/> <p style="text-align: center;">Signature</p> <p style="text-align: center;">Lisa M. Hemmendinger</p> <hr/> <p style="text-align: center;">Typed or printed name</p> <p style="text-align: center;">202-824-3000</p> <hr/> <p style="text-align: center;">Telephone number</p> <p style="text-align: center;">July 3, 2007</p> <hr/> <p style="text-align: center;">Date</p>
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<p><input type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>					

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* Application of: )  
 ) Art Unit: 1655  
 GOLZ *et al.* )  
 ) Confirmation No. 7581  
 Serial No.: 10/528,460 )  
 ) Examiner: Bin Shen  
 Filed: March 18, 2005 )  
 ) Atty Docket No.: 004974.01083

For: **Diagnostics and Therapeutics for Diseases Associated  
with Human Phosphodiesterase 11A (PDE11A)**

**REASONS SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW**

U.S. Patent and Trademark Office  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

This paper accompanies a Pre-Appeal Brief Request for Review and a Notice of Appeal. Claims 1 and 5-11 are pending and are rejected under 35 U.S.C. § 102(b) and § 103(a). There are clear errors in these rejections.

Independent claim 1 is directed to a method of screening for candidate therapeutic agents. The method comprises steps of (i) contacting a test compound with a PDE11A polypeptide, (ii) detecting binding of said test compound to said PDE11A polypeptide, and (iii) identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said

PDE11A polypeptide. Claim 1 and dependent claims 5-9 are rejected under 35 U.S.C. § 102(b) as anticipated by Yuasa.<sup>1</sup> A secondary reference (Lanfear<sup>2</sup>) is added to Yuasa to reject claim 1 and dependent claims 4-11 under 35 U.S.C. § 103(a). The Examiner did not properly apply controlling legal precedent with respect to either rejection.

Rejection Under 35 U.S.C. § 102(b)

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Yuasa does not expressly disclose step (iii) of claim 1 (“identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said PDE11A polypeptide”). The Examiner points to page 31469, right column, 2<sup>nd</sup> full paragraph of Yuasa and contends that Yuasa teaches that “each PDE plays a distinct physiological role in different tissues and cells and may be valuable pharmacological targets.” This is merely a generic teaching that does not expressly or inherently link PDE11A to any of the particular disorders recited in independent claim 1.

Moreover, to establish inherency, extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.” *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1759 (Fed. Cir. 1991) (emphasis added). The Examiner points to page 31478, right column, lines 1-4, where Yuasa teaches that “[t]he PDE inhibitors, 3-

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<sup>1</sup> Yuasa *et al.*, *J. Biol. Chem.* 275, 31469-79, 2000.

<sup>2</sup> Lanfear *et al.*, US 2002/0115176.

isobutyl-1-methylxanthine and papaverine, also initiate morphologic differentiation in human prostate cancer cells and inhibit the proliferation and invasive potential of the cells.” In fact, the cited portion of Yuasa teaches that “[i]n prostate, PDEs have been little studied” and that the PDE inhibitor studies and other reports “suggest that the involvement of a cAMP and cGMP PDE, PDE11A, in controlling prostate or testis functions is plausible.” Paragraph bridging the left and right columns on page 31478. This is not an inherent anticipation of the claimed method.

Rejection Under 35 U.S.C. § 103(a)

Lanfear<sup>3</sup> is added to Yuasa to reject claims 1 and 4-11 under 35 U.S.C. § 103(a). A *prima facie* case requires three elements:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Manual of Patent Examining Procedure, 8<sup>th</sup> ed., § 2142. As explained above, Yuasa does not teach or suggest step (iii) of independent claim 1. Lanfear also does not teach or suggest this step. Claims 1 and 4-11 are therefore not *prima facie* obvious over the cited combination.

Respectfully submitted,

BANNER & WITCOFF, LTD.

/Lisa M. Hemmendinger/

Date: July 3, 2007

By: \_\_\_\_\_

Customer Number: 22907

Lisa M. Hemmendinger  
Registration No. 42,653

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<sup>3</sup> Lanfear *et al.*, US 2002/0115176.